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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,744	03/22/2002	Willy Delcersnijder	01975.0034	5092

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,744	DELEERSNIJDER ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-69* is/are pending in the application.

4a) Of the above claim(s) *22-25,27,30,32,35,37,47,49,51,57-59 and 61-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-21,26,28,29,31,33,34,36,38-46,48,50,52-56,60,68 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/27/02 11/17/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1, 2 and 5 to 69 are pending in the instant application.

2) The instant specification does not comply with 37 C.F.R. § 1.77, which requires that:

(a) The elements of the application, if applicable, should appear in the following order:

(1) Utility Application Transmittal Form.

(2) Fee Transmittal Form.

(3) Title of the invention; or an introductory portion stating the name, citizenship, and residence of the applicant, and the title of the invention.

(4) Cross-reference to related applications.

(5) Statement regarding federally sponsored research or development.

(6) Reference to a "Microfiche appendix." (See § 1.96 (c)). The total number of microfiche and total number of frames should be specified.

(7) Background of the invention.

(8) Brief summary of the invention.

(9) Brief description of the several views of the drawing.

(10) Detailed description of the invention.

(11) Claim or claims.

(12) Abstract of the Disclosure.

(13) Drawings.

(14) Executed oath or declaration.

(15) Sequence Listing (See § § 1.821 through 1.825).

(b) The elements set forth in paragraphs (a)(3) through (a)(5), (a)(7) through (a)(12) and (a)(15) of this section should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading. [43 FR 20464, May 11, 1978; 46 FR 2612, Jan. 12, 1981; paras. (h) and (i), 48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996].

Correction is required.

3) Claims 22 to 25, 27, 30, 32, 35, 37, 47, 49, 51, 57 to 59 and 61 to 67 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper filed 08 January of 2004. The traversal is on the ground(s) that "all of the claims relate to the IGS4 G-protein coupled receptors". This is not found persuasive because they do not "relate" to a common special technical feature as defined in 37 C.F.R. 1.475:

"37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. "

As indicated in the original requirement, the nucleic acids and proteins of invention I, for example, do not share a distinguishing technical relationship with the antibody of invention II. Invention II encompasses an antibody that binds to any epitope found in the polypeptide of invention I, which may also be shared with any number of other G protein-coupled receptors. Invention III encompasses a method of administering nueromedin, a compound Applicant has conceded was known in the prior art and, therefore, can not serve as a distinguishing special technical feature. Further, even though the different compounds are classified differently, different classification is not a criteria in determining lack of unity in an application filed under 37 C.F.R. 371 The requirement is still deemed proper and is therefore made FINAL.

It is noted that claim 47 was inadvertently included in Group I of the original restriction requirement even though it clearly is drawn to a method of treating that is a non-elected invention. Therefore, claim 47 has been withdrawn from further consideration.

4) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the amino acid sequence presented in line 15 on page 15 of the instant specification. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

5) Claims 14, 18, 21, 36 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a

previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 14, for example, can not properly depend from claim 9 either directly or indirectly because claim 14 can be infringed by a membrane composition which does not contain the expression system of claim 9. Claim 18 can not properly depend from claim 17 because claim 18 is broader in scope than claim 17.

6) Claim 36 is objected to because of the following informalities:

The text "produced by a the method" is grammatically incorrect.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 6, 8, 17, 18, 26, 31, 39, 40, 42, 43, 52, 53, 68 and 69 are rejected under 35 U.S.C. § 101 because they are drawn to non-statutory subject matter. Claim 6, for example, is drawn to a nucleotide "sequence". A "sequence" is a property of a compound and properties, such as shapes, sizes, colors and sequences are not subject to patentability. Claim 18 encompasses a polypeptide as it occurs in nature which, therefore, is not new.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8) Claims 6 to 16, 18 to 20, 28, 29, 31, 33, 34, 36, 42 to 45, 48, 50, 54 to 56, 60, 68 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention .as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate is scope with the claims.

The sole material distinguishing limitation recited in claims 6, 7, 10, 19, 20, 28, 31, 33, 34, 42, 44, 45, 48, 50, 54 and 56 is the term "IGS4 neuromedin receptor protein". This term appears to be defined in the text on page 16 of the instant specification exclusively in functional terms. As such, claims 6, 7, 10, 19, 20, 42, 44, 45 and 54 are essentially single means claims since they encompass any compound having the recited functions irrespective of the structure of that compound. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the

inventor. See M.P.E.P. 2164.08(a). The only "IGS4 neuromedin receptor protein" that is described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is a protein comprising any one of the four amino acid sequences presented in SEQ ID NO:2, 4, 6 and 8 of the instant application. Because these four sequences appear to correspond to alternate embodiments (isoforms) encoded by of a single gene, they do not constitute a representative number of species within the genus of proteins encompassed by the instant claims.

In so far as claims 6 to 16, 18 to 20, 28, 29, 31, 33, 34, 36, 42 to 45, 48, 50, 54 to 56, 60, 68 and 69 require an isolated nucleic acid encoding a "neuromedin receptor protein" lacking one of the four disclosed amino acid sequences or a protein encoded thereby, the instant specification provides neither a written description of such a nucleic acid or protein, or the guidance needed to produce it. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means

as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of isolated DNAs encoding four particular neuromedin receptor proteins having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all neuromedin receptor proteins. Whereas the instant specification may identify some properties which are common to the four neuromedin receptor proteins that are disclosed in the instant specification, it does not identify those defining structural elements which provide the functional and structural properties of any and all neuromedin receptor proteins.

Further, claim 9, for example, allows one to alter up to 20% of the amino acid residues in any one of the four disclosed amino acid sequences. However, the instant specification does not provide the guidance that would be needed by a artisan to produce a functional neuromedin receptor protein having anything other than one of the four naturally occurring amino acid sequences presented in the instant specification

without resorting to a substantial amount of undue experimentation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

In the instant case, the specification does not identify those amino acid residues in the amino acid sequence presented in any one of SEQ ID NOs:2, 4, 6 or 8 of the instant application which are critical to the structural and functional integrity of a neuromedin receptor protein and those residues which are expendable. The instant specification does not identify even a single structurally and functionally related protein in the prior art for which this information is known and could be applied to one or more of those fopur sequences by analogy. Whereas the instant claims encompass an extraordinarily large number of non-naturally occurring neuromedin receptor proteins having a substantial number of modifications relative to those four, naturally occurring proteins which are

described in the instant specification, there is not even a single working example of a modified neuromedin receptor protein. In the complete absence of guidance or working examples an artisan can not make a recombinant neuromedin receptor protein whose amino acid sequence differs from that of SEQ ID NO:2, 4, 6 or 8 by even a single amino acid and predict "by resort to known scientific law" if the modified protein will function as a neuromedin receptor proteins. And if the modified protein does not function as a neuromedin receptor protein, the instant specification does not disclose how to use it.

9) Claims 1, 2, 5, 7 to 9, 11 to 17, 31, 36, 41 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims expressly require the deposited material recited therein. Applicant, their assignee or their agent needs to provide a declaration containing the following:

> The identification of the declarant.
>
> A statement that a deposit has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
>
> A statement that the deposited material has been accorded a specific, recited, accession number.
>
> A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. ' 122.

> A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.
>
> A statement by declarant that all statement made therein of declarant's knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternately, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession number) number, name and address of the depository, and the complete taxonomic description.

.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10) Claims 1, 2, 5 to 21, 26, 28, 29, 31, 33, 34, 36, 38 to 46, 48, 50, 52 to 56, 60, 68 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10.1) Claims 1, 2, 5 to 21, 26, 28, 29, 31, 33, 34, 36, 38 to 46, 48, 50, 52 to 56, 60, 68 and 69 are vague and indefinite in so far as they employ the term "IGS4" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an "IGS4" polypeptide an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Whereas the text on pages 12 to 14 of the instant specification identifies some material that is encompassed by this term, it does not precisely identify that subject mater that is excluded by this term. This limitation is vague and indefinite because it is unclear how "an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2" would materially differ from "an isolated IGS4 polypeptide comprising the amino acid sequence of SEQ ID NO:2".

10.2) Claims 7, 8, 10, 20, 21, 43, 46, 54 and 60 are vague and indefinite because it is unclear how a polypeptide can exhibit expression. It has been well settled in the art of molecular biology that the expression of a protein in a given tissue or organ is a function of that tissue or organ, not a function of the polypeptide.

10.3) Claims 8, 19 to 21, 28, 33, 34, 43, 45, 46, 50 and 60 are vague and indefinite because the "high affinity" is conditional and no single set of defining conditions can be found in the claims or the specification.

10.4) Claims 28, 33, 34 and 38 are vague and indefinite because there is no antecedent basis for "the IGS4 neuromedin receptor protein" or "IGS4 receptor". Neither the art of record nor the instant specification identifies a single protein "the IGS4

neuromedin receptor protein. Claims 48 and 50 are vague and indefinite in so far as they depend from any one of claims 28, 33 or 34 for this element.

10.5) Claim 29 is vague and indefinite because there is no antecedent basis for "the IGS4 neuromedin receptor protein according to claim 28", which is drawn to "a method of identifying agonists".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 6, 7, 19, 20, 42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by the Tan et al. publication (Genomics 52:223-229, Jun. 1998, cited by Applicant) in light of the Fujii et al. publication (J. Biol. Chem. 275:21068-21074, Jul. 2000, cited by Applicant). Figure 2 of the Tan et al. publication described an isolated nucleic acid encoding an orphan G protein-coupled receptor identified therein as FM-3, and the protein encoded thereby, as well as a replication vector and host cell containing that vector. The Fujii et al. publication disclosed the fact that the isolated receptor described in the Tan et al. publication was a neuromedin receptor. Because the instant claims are only functionally defined and fail to recite any distinguishing structural feature, they encompass any isolated nucleic acid encoding a neuromedin receptor and the receptor encoded thereby.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600